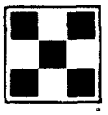

Purina Mills, Inc.

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

October 1, 1999

(Docket No. 99D-2638)
Use of Medicated Feeds for Minor Species
Draft Compliance Policy Guide

Purina Mills Inc. is a major manufacturer and distributor of animal feed, including minor species feed, and therefore has a vital interest in the agencies draft Compliance Policy Guide for use of medicated feeds for minor species. Considering the need of medication for minor species, and the few animal drugs that have been approved for such minor species purposes, Purina is very supportive of the agencies efforts to make needed drugs available, consistent with human and animal safety considerations. Further, in some cases, the only practical means of getting medication to animals is through the feed.

Purina applauds the agency for the direction and regulatory program that this policy guide will establish. This policy will be of value to the minor species animal feeders and to the improvement in animal health. The policy establishes a regulatory program between the minor species animal feeder and their respective veterinarian. The medicated feed provider is required to label such feed in accordance with the animal drugs respective approval. The veterinarian is responsible for providing the minor species feeder with appropriate directions for use. The veterinarian is also responsible for seeing that animal and human safety issues are addressed, as has been established by the present minor species extra label use of dosage form drugs. Purina believes that this scheme will work well.

However, Purina does not believe that this policy goes far enough. The feed provided may not be nutritionally or physically adequate for the minor species to be fed. As proposed, game birds may be fed turkey or poultry diets, an elk may be fed a cattle feed, etc. There is tremendous need today to provide dewormers and other needed medications in many varied animal species feeds. Such species could include, Addax, Aoudad, Bison, Blackbuck Antelope, Defassa Waterbuck, Eland, Elk, Deer, Zebra, Impalla, Llama, Mini Horses, Mouflon, Nilgal, Rhino, Watusi, Water Buffalo, Gnu, Miniature Mule, Gensbok, Wild Burrow, Mutjac, Kudu, Giraffe, Perbelly, Camel, Pigmy Goats, Pheasant, Rabbit,

99D-2638

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Monkey, lizard, peacock, Yellowhead Amazon, Ducks, Prarie Dog, Raccoon, Wolf, Couti, Virvit, Goats, Sugar Glider, Macaw, Parrot, Cockatiel, Tiger, Lion., Cougar, Jaguar, Ostirch, Emu, Rhea, and laboratory rats and mice. This list is certainly not meant to be all inclusive. The list is simply to demonstrate the vast number of minor species in need of medication and differences in the nutritional needs of these animals. In addition to nutritional differences in these diets, there is also physical differences in pellet or crumble size that can impact the palatability and/or ability of the animal to appropriately consume and/or metabolize the diet.

Instead of having to provide feed formulated specifically for a major food animal as would be established by this policy guide, Purina suggests that a feed provider have the ability to provide a customer-formulated diet, as defined by the Association of American Feed Control Officials in their Official Publication where the need exists. The drug, drug level, directions for use, and indications for use would all continue to be consistent with the major food animal FDA approval. To accomplish this, Purina respectfully suggests that the following language changes to the draft.

- In the "Guidance" section, "Under this guidance, the agency ordinarily will not consider regulatory action if: 1. The medicated feed is approved for use in food-producing animal and is formulated and labeled according to its approved labeling, as described in the code of Federal Regulations (21 CFR part 558)." add the words, "except that such feed may be formulated nutritionally and/or physically manufactured for the intended minor species. In such cases, the feed must be customer-formula feed as defined by the Official Publication of the Association of American Feed Control Officials for the minor species feeder and the feed label must show the drug level, indications for use, feeding directions and claim consistent with the major animal species approval (21 CFR part 558). However, in addition the feed label may show the minor animal species for which the feed has been customer-formula manufactured and feed guarantees and ingredient listing reflecting the feed formulation."

- In the "Regulatory Guidance" section of the guide, the sentence "If the feed is not formulated and labeled in accordance with the approved conditions of use as described in the code of Federal Regulations, add the words, "and the Official Publication of the Association of American Feed Control Officials."

These changes will permit zoo animals, and other minor species animals to receive medication through recommendations of their veterinarian, yet also receive appropriate nutritional and physical form needs in their diet.

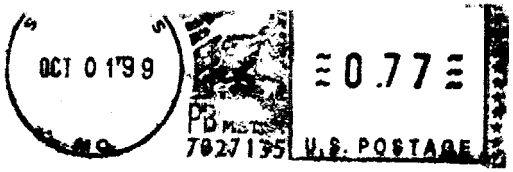
Again, Purina is very supportive of the agencies efforts to bring needed medication to minor species animals consistent with animal and human safety considerations. Purina believes that this Compliance Policy Guide, amended as suggested above, will accomplish these objectives. Without the suggested modifications, some minor species animals will receive needed medication, but a great number will not because of nutritional and physical form issues.

Purina Mills appreciates this opportunity to comment and trusts that the agency will find our comments useful. If there is need for further information or clarification of our comments, please phone me 314 768-4492.

Sincerely,

R. E. Broyles, Director
Regulatory & Quality

cc American Feed Industry Association
National Grain and Feed Association



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